

REMARKS/ARGUMENTS

Claims 25-35 stand allowed. Claims 4, 7-11, 20 and 22-24 have not been substantively been amended, but rather, claims 4, 20 and 22 have been rewritten in independent form and now stand allowable consistent with the Examiner's comments. Claim 5 has been amended to depend from claim 4 and claims 6 through 11 therefore depend from claim 4 or an intervening claim and should likewise be allowable. Claims 23 and 24 depend from rewritten claim 22 and should likewise be allowable.

Claims 1, 12, 13, 16 are amended, and claim 21 is cancelled.

Reconsideration of this application is respectfully requested in view of the above amendments to the claims and the following remarks.

I. Claim Rejections Under 35 U.S.C. § 102(b)

In connection with the matters contemplated herein, Applicant respectfully notes that the following discussion should not be construed to constitute an exhaustive enumeration of the distinctions between the claims of the present application and the references cited by the Examiner. Instead, such distinctions are presented solely by way of example. Consistent with the foregoing, the discussion herein is not intended, and should not be construed, to prejudice or foreclose future consideration, by the Applicant, of additional or alternative distinctions between the claims of the present application and the references cited by the Examiner.

Applicant notes further that a claim is anticipated under 35 U.S.C. § 102(a), (b), or (e) only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. Further, the identical invention must

be shown in as complete detail as is contained in the claim. Finally, the elements must be arranged as required by the claim. See Manual of Patent Examining Procedure ("M.P.E.P.") § 2131.

A. Claims 1-3

The Examiner has rejected independent claim 1 under 35 U.S.C. § 102(b) as being anticipated by U.S. 5,615,439 issued to *Bourrelly* ("Bourrelly"). The Examiner suggests that *Bourrelly* discloses a "brush comprising an atraumatic tip (118, 218), fill wire (114'), shaft (110'), inner sheath (120'a) and outer sheath (126') (see fig 1A) and further wherein the brush is adapted to clean passageways in medical devices." Applicant respectfully disagrees with the contentions of the Examiner and submits that, at least in view of the amendment submitted herewith, *Bourrelly* fails to anticipate independent claim 1.

As amended herein, claim 1 requires, among other things, a "permanent inner sheath covering at least a portion of said fill wire" (emphasis added). In contrast, *Bourrelly* makes clear that the inner sheath (support member 120) "is dismountable and may be mounted or dismounted on the first end of the rod by screwing movement relative to the brush" because of the importance of cleaning and decontaminating the device (Col. 4, lines 9-14) (emphasis added). Further, *Bourrelly* confirms in its claims that the support member is to be mounted by a screwing motion relative to the brush (see, e.g., claims 5, 6). Therefore, *Bourrelly* fails to teach that its inner sheath is permanent.

Applicant respectfully submits that because the reference cited by the Examiner fails to disclose each and every element as set forth in amended claim 1, that reference fails to anticipate claim 1, and likewise fails to anticipate claims 2-3 depending

therefrom. Applicant thus respectfully submits that for at least the foregoing reason, the Examiner's rejection of claims 1-3 has been overcome and should be withdrawn.

B. Claims 12 – 14

The Examiner has rejected independent claim 12 under 35 U.S.C. § 102(b) as being anticipated by five U.S. patents. Applicant respectfully disagrees with the contentions of the Examiner and submits that, at least in view of the amendment submitted herewith, each patent fails to anticipate independent claim 12.

1. *Gunjian*

The Examiner has rejected independent claim 12 under 35 U.S.C. § 102(b) as being anticipated by U.S. 4,819,291 issued to *Gunjian* ("*Gunjian*"). The Examiner has suggested that *Gunjian* discloses "a brush (10) for cleaning the passageway in a device (28) comprising a shaft (20), means (24 or even handle 12) transmitting a cleaning force exerted on the shaft and an outer sheath (18) covering at least a portion of the shaft (20)." Applicant respectfully disagrees with the contentions of the Examiner and submits that, at least in view of the amendment submitted herewith, *Gunjian* fails to anticipate independent claim 12.

As amended herein, claim 12 requires, among other things, a "permanent inner sheath covering at least a portion of fill wire" (emphasis added). As *Gunjian* fails to disclose, among other things, the aforementioned limitation of amended claim 12, Applicant respectfully submits that *Gunjian* fails to anticipate claim 12, and submits that the Examiner's rejection of claim 12 has been overcome and should be withdrawn.

2. *Watanabe*

The Examiner has rejected independent claim 12 under 35 U.S.C. § 102(b) as being anticipated by U.S. 4,889,106 issued to *Watanabe* ("*Watanabe*"). The Examiner has suggested that *Watanabe* discloses "a brush (30) for cleaning a passageway in a medical device (10) comprising a shaft (31), means (34) for transmitting a cleaning force exerted on the shaft and an outer sheath (33) covering at least a portion of the shaft." Applicant respectfully disagrees with the contentions of the Examiner and submits that, at least in view of the amendment submitted herewith, *Watanabe* fails to anticipate independent claim 12. As amended herein, claim 12 requires, among other things, a "permanent inner sheath covering at least a portion of fill wire" (emphasis added). As *Watanabe* fails to disclose, among other things, the aforementioned limitation of amended claim 12, Applicant respectfully submits that *Watanabe* fails to anticipate claim 12, and submits that the Examiner's rejection of claim 12 has been overcome and should be withdrawn.

3. *Cox*

The Examiner has rejected independent claim 12 under 35 U.S.C. § 102(b) as being anticipated by U.S. 5,297,310 issued to *Cox* ("*Cox*"). The Examiner has suggested that *Cox* discloses "a brush (10) for cleaning passageways in medical devices comprising a shaft (15), outer sheath (11) and fill wire (the right portion of fig 3) provided with an atraumatic tip (12) and which reads on the recited 'means for transmitting,'" Applicant respectfully disagrees with the contentions of the Examiner and submits that, at least in view of the amendment submitted herewith, *Cox* fails to anticipate independent claim 12 .

As amended herein, claim 12 requires, among other things, a "permanent inner sheath covering at least a portion of fill wire" (emphasis added). As *Cox* fails to disclose, among other things, the aforementioned limitation of amended claim 12, Applicant respectfully submits that *Cox* fails to anticipate claim 12, and likewise fails to anticipate claim 13 depending therefrom. For at least the foregoing reason, Applicant submits that the Examiner's rejection of claims 12 and 13 has been overcome and should be withdrawn.

4. *Poje*

The Examiner has rejected independent claim 12 under 35 U.S.C. § 102(b) as being anticipated by U.S. 5,297,310 issued to *Poje* ("Poje"). The Examiner has suggested that *Poje* discloses "a brush for cleaning passageways in medical devices comprising a shaft (18), means in the form of a fill wire (14,26) and an atraumatic tip (44) for transmitting a cleaning force and an outer sheath (16)." Applicant respectfully disagrees with the contentions of the Examiner and submits that, at least in view of the amendment submitted herewith, *Poje* fails to anticipate independent claim 12.

As amended herein, claim 12 requires, among other things, a "permanent inner sheath covering at least a portion of a fill wire" (emphasis added). As *Poje* fails to disclose, among other things, the aforementioned limitation of amended claim 12. Applicant respectfully submits that *Poje* fails to anticipate claim 12, and likewise fails to anticipate claim 13 depending therefrom. For at least the foregoing reason, Applicant submits that the Examiner's rejection of claims 12 and 13 has been overcome and should be withdrawn.

5. *Bourrelly*

The Examiner has rejected independent claim 12 under 35 U.S.C. § 102(b) as being anticipated by U.S. 5,615,439 issued to *Bourrelly* ("*Bourrelly*"). The Examiner has suggested that *Bourrelly* discloses "a brush comprising an atraumatic tip (118,218) fill wire (114), shaft (110), inner sheath (120'a) and outer sheath (126') (see fig 1a) and further wherein the brush is adapted to clean passageways in a medical device."

Applicant respectfully disagrees with the contentions of the Examiner and submits that, at least in view of the amendment submitted herewith, *Bourrelly* fails to anticipate independent claim 12.

As amended herein, claim 12 requires, among other things, a "permanent inner sheath covering at least a portion of fill wire" (emphasis added). In contrast, *Bourrelly* makes clear that the inner sheath (support member 120) "is dismountable and may be mounted or dismounted on the first end of the rod by screwing movement relative to the brush" because of the importance of cleaning and decontaminating the device (col. 4, lines 9-14) (emphasis added). Further, *Bourrelly* confirms in its claims that the support member is to be mounted by a screwing motion relative to the brush (see, e.g., claims 5, 6). Therefore, *Bourrelly* fails to teach that its inner sheath is permanent.

Applicant respectfully submits that because the reference cited by the Examiner fails to disclose each and every element as set forth in amended claim 12, that reference fails to anticipate claim 12, and likewise fails to anticipate claims 12-14 depending therefrom. Applicant thus respectfully submits that for at least the foregoing reason, the Examiner's rejection of claims 12-14 has been overcome and should be withdrawn.

C. Claims 16-18

The Examiner has rejected independent claim 16 under 35 U.S.C. § 102(b) as being anticipated by U.S. 5,615,439 issued to *Bourrelly* ("*Bourrelly*"). Applicant respectfully notes that the *Bourrelly* discussion of the rejection of claims 12-14 above, are equally germane with respect the obviousness rejection of claims 16-18, and respectfully directs the attention of the Examiner such discussion.

II. Claim Rejections Under 35 U.S.C. § 103(a)

Applicant respectfully notes at the outset that in order to establish a *prima facie* case of obviousness, it is the burden of the Examiner to demonstrate that three criteria are met: first, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings; second, there must be a reasonable expectation of success; and third, the prior art reference (or references when combined) must teach or suggest all the claim limitations. See M.P.E.P. § 2143.

The Examiner has rejected claims 5, 6, 15, 19, and 21 under 35 U.S.C. § 103 as being unpatentable over *Bourrelly*. The Examiner alleges that *Bourrelly* "discloses the invention substantially as claimed with the exception of the shaft being a memory alloy, in particular NiTiNOL." The Examiner further alleges that "it would have been obvious to one of ordinary skill to have modified the shaft to be of such an alloy."

A. *Alleged Obviousness of Claims 5, 6, 15, 19, and 21*

1. **Claim 5**

Claim 5 has been amended to depend from claim 4 which has been rewritten in independent form. Thus, in that rewritten claim 4 now stands allowable, claim 5 is likewise allowable in that it depends from claim 4.

2. **Claim 6**

It appears that the Examiner has rejected claim 6 based on the Examiner's asserted belief that "it would have been obvious to one of ordinary skill" to have modified the shaft to be of a memory alloy, in particular NiTiNOL. Applicant respectfully disagrees with the contention of the Examiner but submits that, in light of the discussion below, the Examiner has nonetheless failed to establish a *prima facie* case of obviousness with respect to claim 6.

While the assertion of the Examiner seems to take for granted that it would have been obvious to modify the shaft to be an alloy, *Bourrelly* fails to either teach or suggest such a modification. Concerning the composition of the shaft, *Bourrelly* states that the "outside surface of the [shaft] element is smooth" by use of some kind of plastic material. *Bourrelly* states that the shaft may be constituted by a "smooth rod of plastics material;" or by a "reinforced plastics rod;" or by being merely coated in "plastics material" (col. 2, lines 56-62). There is absolutely no discussion or teaching in *Bourrelly* that suggests the shaft consists of a metal alloy.

Although *Bourrelly* does teach or suggest modifications that the coupling sleeve and the end pieces may be made of metal (metal described as a "rigid part" and not "smooth") (col. 4, lines 21-22; col. 5, lines 31-32), there is no such teaching or

modification concerning the shaft anywhere in the patent. Therefore, this purposeful lack of teaching or modification concerning the shaft shows that *Bourrelly* did not intend the shaft to consist of a metal alloy.

Applicant thus respectfully submits that the Examiner has failed to establish a prima facie case of obviousness with respect to claim 6, at least because *Bourrelly* fails to teach or suggest the modifications proposed by the Examiner. Applicant thus respectfully submits that for at least the foregoing reason, the Examiner's rejection of claim 6 has been overcome and should be withdrawn.

3. Claims 15, 19, 21

Applicant respectfully notes that the discussion of the obviousness rejection of claims 15 and 19 above, are equally germane with respect to the obviousness rejection of claim 6, and respectfully directs the attention of the Examiner to such discussion. Claim 21 has been cancelled.

CONCLUSION

In view of the response and amendments submitted herein, Applicant respectfully submits that each of the pending claims is in condition for allowance. Therefore, reconsideration of the rejections is requested and allowance of those claims is respectfully solicited. In the event that the Examiner finds any remaining impediment to a prompt allowance of this application that could be clarified in a telephonic interview, the Examiner is respectfully invited to initiate the same with the undersigned attorney.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "John C. Stringham", with a long horizontal flourish extending to the right.

JOHN C. STRINGHAM
Attorney for Applicant
Registration No. 40,831

WORKMAN NYDEGGER
1000 Eagle Gate Tower
60 East South Temple
Salt Lake City, UT 84111
Telephone: (801) 533-9800
Fax: (801) 328-1707

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